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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PURPLE BIOTECH LTD., **Plaintiff,** **v.** **LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,** **Defendants.**	**Civil Action No. 3:20-cv-12849 (CCC)(MF)** **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Purple Biotech Ltd. ("Purple Biotech"), by its undersigned attorneys, for its Complaint against defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. ("LPI") (collectively "Lupin"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Lupin's filing of an Abbreviated New Drug

Application ("ANDA") No. 215112 ("Lupin's ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Purple Biotech's 2.5 mg/200 mg, 5 mg/200 mg, 10 mg/200 mg Consensi™ drug products ("Lupin's ANDA Products") prior to the expiration of United States Patent Nos. 10,350,171 (the "'171 patent"), 9,408,837 (the "'837 patent"), 10,925,835 (the "'835 patent"), and 10,945,960 (the "'960 patent"), all owned or exclusively licensed by Purple Biotech (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Purple Biotech (formerly known as Kitov Pharma Ltd.) is a biopharmaceutical company committed to improving the lives of patients worldwide. Purple Biotech focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Purple Biotech is a corporation organized and existing under the laws of Israel, having a principal place of business at One Azrieli Center Round Tower, Floor 19, 132 Menachem Begin Road, Tel Aviv 670110 Israel.

3. Upon information and belief, defendant Lupin Ltd. is an Indian company, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India 107.

4. Upon information and belief, LPI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, LPI is a wholly owned subsidiary of Lupin Ltd. and acts as its authorized agent in the United States.

The Patents-in-Suit

5. On July 16, 2019, the USPTO duly and lawfully issued the '171 patent, entitled, "Celecoxib and Amlodipine Formulation and Method of Making the Same" to Kitov and Dexcel Pharma Limited as co-assignees of inventor Yitshak I. Efrati. Purple Biotech owns all assertion rights to the '171 patent. A copy of the '171 patent is attached hereto as Exhibit A.

6. On August 9, 2016, the USPTO duly and lawfully issued the '837 patent, entitled, "Ameliorating Drug-Induced Elevations in Blood Pressure by Adjunctive Use of Antihypertensive Drugs" to Kitov as assignee of the inventors, Peter C. Hoyle, and Paul Waymack. A copy of the '837 patent is attached hereto as Exhibit B.

7. On February 23, 2021, the USPTO duly and lawfully issued the '835 patent, entitled, "Celecoxib and Amlodipine Formulation and Method of Making the Same" to Kitov and Dexcel Pharma Limited as co-assignees of the inventor, Yitshak Itsik Efrati. A copy of the '835 patent is attached hereto as Exhibit C.

8. On March 16, 2021, the USPTO duly and lawfully issued the '960 patent, entitled, "Celecoxib and Amlodipine Formulation and Method of Making the Same" to Purple Biotech and Dexcel Pharma Limited as co-assignees of the inventor, Yitshak Itsik Efrati. A copy of the '960 patent is attached hereto as Exhibit D.

The Consensi™ Drug Product

9. Purple Biotech's U.S. distribution partner, Coeptis Pharmaceutical Inc., holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for Amlodipine Besylate/Celecoxib Tablets, 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg, (NDA No. 210045), which it sells under the trade name Consensi™. Consensi™ is a fixed-dose combination of celecoxib and amlodipine besylate for the simultaneous treatment of osteoarthritis pain and hypertension. The claims of the patents-

in-suit cover, inter alia, pharmaceutical compositions, methods of manufacturing, and methods of use.

Jurisdiction and Venue

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Lupin because, *inter alia*, Lupin has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including in New Jersey. Upon information and belief, following approval of Lupin's Abbreviated New Drug Application ("ANDA") No. 215112, Lupin will make, use, import, sell, and/or offer for sale its proposed generic versions of Consensi™ brand products in the United States, including in New Jersey, prior to the expiration of the patents-in-suit. This Court has personal jurisdiction over Lupin for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

12. This Court also has personal jurisdiction over Lupin by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of the laws of New Jersey by engaging in systematic and continuous contacts with New Jersey. Upon information and belief, LPI, a wholly owned subsidiary of Lupin Ltd., maintains a physical presence in New Jersey with its manufacturing and research and development facility located in New Jersey, and is registered to do business in New Jersey. Upon information and belief, Lupin regularly and continuously transacts business within New Jersey, including by developing, manufacturing, marketing, and selling generic pharmaceutical products. Upon information and belief, Lupin derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of

conducting business within New Jersey.

13. Upon information and belief, Lupin Ltd. and LPI are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to Lupin's proposed product that is the subject of ANDA No. 215112, for which Lupin has sought approval from the FDA.

14. Upon information and belief, Lupin Ltd., alone and/or together with its affiliate and agent, LPI, filed or caused to be filed ANDA No. 215112 with the FDA.

15. Upon information and belief, Lupin has continuously placed its products into the stream of commerce for distribution and consumption in the State of New Jersey and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

16. This Court also has personal jurisdiction over Lupin Ltd. and LPI because they have previously been sued numerous times in this Judicial District and have not challenged personal jurisdiction, and Lupin Ltd. has purposefully availed itself of the rights and benefits of the jurisdiction of this Court by filing counterclaims in this Judicial District. See, e.g., *Mitsubishi Tanabe Pharma Corp. v. Lupin Ltd.*, Civil Action No. 19-07165, D.I. 8 (D.N.J. Apr. 3, 2019) (Lupin Ltd. not contesting personal jurisdiction or venue and asserting counterclaims); *Sun Pharma Global FZE, et al. v. Lupin Ltd., et al.*, Civil Action No. 18-02213, D.I. 60 (D.N.J. Jan. 29, 2019) (Lupin Ltd. and LPI not contesting personal jurisdiction or venue and Lupin Ltd. asserting counterclaims); *Horizon Therapeutics, Inc. v. Lupin Ltd., et al.*, Civil Action No. 15-07624, D.I. 40 (D.N.J. Apr. 25, 2016) (Lupin Ltd. and LPI not contesting personal jurisdiction or venue and Lupin Ltd. asserting counterclaims); *Senju Pharmaceutical Co., Ltd., et al. v Lupin*

Ltd., et al., Civil Action No. 14-00667, D.I. 7 (D.N.J. Mar. 27, 2014) (Lupin Ltd. and LPI not contesting personal jurisdiction or venue and Lupin Ltd. asserting counterclaims).

17. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Lupin Ltd. in this action, this Court may exercise jurisdiction over Lupin Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Lupin Ltd. is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, by submitting various ANDAs to the FDA and manufacturing and selling pharmaceutical products distributed throughout the United States such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process.

18. Venue is proper in this Judicial District as to Lupin pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Lupin has committed and will commit further acts of infringement in this Judicial District. Venue is also proper in this Judicial District as to Lupin because Lupin has a regular and established place of business in New Jersey, and for other reasons that will be presented to the Court if such venue is challenged.

Acts Giving Rise To This Suit

19. Pursuant to Section 505 of the FFDCA, Lupin filed Lupin's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Amlodipine Besylate/Celecoxib Tablets, 2.5 mg/200 mg, 5 mg/200 mg, and 10 mg/200 mg before the patents-in-suit expire.

20. On information and belief, following FDA approval of Lupin's ANDA, Lupin will make, use, sell, or offer to sell Lupin's ANDA Products throughout the United States, or import such generic products into the United States.

21. On information and belief, in connection with the filing of its ANDA as described above, Lupin provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Lupin's Paragraph IV Certification"), alleging that the claims of '171 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Lupin's ANDA.

22. No earlier than August 4, 2020, Lupin sent written notice of its Paragraph IV Certification to Purple Biotech ("Lupin's Notice Letter"). Lupin's Notice Letter alleged that the claims of the '171 patent are invalid and/or will not be infringed by the activities described in Lupin's ANDA. Lupin's Notice Letter also informed Purple Biotech that Lupin seeks approval to market Lupin's ANDA Products before the '171 patent expires.

Count I: Infringement of the '171 Patent

23. Purple Biotech repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

24. Lupin, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '171 patent.

25. Lupin's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '171 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

26. There is a justiciable controversy between the parties hereto as to the infringement of the '171 patent.

27. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '171 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States.

28. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '171 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '171 patent and knowledge that its acts are encouraging infringement.

29. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '171 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's ANDA Products are especially adapted for a use that infringes one or more claims of the '171 patent and that there is no substantial non-infringing use for Lupin's ANDA Products.

30. Purple Biotech will be substantially and irreparably damaged and harmed if Lupin's infringement of the '171 patent is not enjoined.

31. Purple Biotech does not have an adequate remedy at law.

32. This case is an exceptional one, and Purple Biotech is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '837 Patent

33. Purple Biotech repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

34. Lupin, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '837 patent.

35. Lupin's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '837 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

36. There is a justiciable controversy between the parties hereto as to the infringement of the '837 patent.

37. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '837 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States.

38. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '837 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '837 patent and knowledge that its acts are encouraging infringement.

39. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '837 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's

ANDA Products are especially adapted for a use that infringes one or more claims of the '837 patent and that there is no substantial non-infringing use for Lupin's ANDA Products.

40. Purple Biotech will be substantially and irreparably damaged and harmed if Lupin's infringement of the '837 patent is not enjoined.

41. Purple Biotech does not have an adequate remedy at law.

42. This case is an exceptional one, and Purple Biotech is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '835 Patent

43. Purple Biotech repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

44. Lupin, by the submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '835 patent.

45. Lupin's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '835 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

46. There is a justiciable controversy between the parties hereto as to the infringement of the '835 patent.

47. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '835 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States.

48. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '835 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '835 patent and knowledge that its acts are encouraging infringement.

49. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '835 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's ANDA Products are especially adapted for a use that infringes one or more claims of the '835 patent and that there is no substantial non-infringing use for Lupin's ANDA Products.

50. Purple Biotech provided the USPTO all of the prior art references cited in Lupin's Notice Letter, and the examiner considered them before issuing the '835 patent.

51. Purple Biotech will be substantially and irreparably damaged and harmed if Lupin's infringement of the '835 patent is not enjoined.

52. Purple Biotech does not have an adequate remedy at law.

53. This case is an exceptional one, and Purple Biotech is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '960 Patent

54. Purple Biotech repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

55. Lupin, by the submission of its Paragraph IV Certification as part of its ANDA to

the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '960 patent.

56. Lupin's submission of its ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's ANDA Products, prior to the expiration of the '960 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

57. There is a justiciable controversy between the parties hereto as to the infringement of the '960 patent.

58. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '960 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States.

59. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '960 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '960 patent and knowledge that its acts are encouraging infringement.

60. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '960 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Lupin's ANDA Products in the United States. On information and belief, Lupin has had and continues to have knowledge that Lupin's ANDA Products are especially adapted for a use that infringes one or more claims of the '960

patent and that there is no substantial non-infringing use for Lupin's ANDA Products.

61. Purple Biotech provided the USPTO all of the prior art references cited in Lupin's Notice Letter, and the examiner considered them before issuing the '960 patent.

62. Purple Biotech will be substantially and irreparably damaged and harmed if Lupin's infringement of the '960 patent is not enjoined.

63. Purple Biotech does not have an adequate remedy at law.

64. This case is an exceptional one, and Purple Biotech is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Purple Biotech respectfully requests the following relief:

(A) A Judgment that Lupin has infringed the patents-in-suit by submitting ANDA No. 215112;

(B) A Judgment that Lupin has infringed, and that Lupin's making, using, offering to sell, selling, or importing Lupin's ANDA Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 215112 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Purple Biotech is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Lupin and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Lupin's ANDA Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Purple Biotech is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Lupin, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any solid forms of amlodipine besylate/celecoxib compositions claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Purple Biotech is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, sale, and/or offer for sale of Lupin's ANDA Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Lupin has committed any acts with respect to amlodipine besylate/celecoxib compositions claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Purple Biotech damages for such acts;

(H) If Lupin engages in the commercial manufacture, use, importation into the United States, sale, and/or offer for sale of Lupin's ANDA Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Purple Biotech resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Purple Biotech its attorneys' fees incurred in this action;

(K) A Judgment awarding Purple Biotech its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: March 26, 2021

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

/s/ Harvey Bartle, IV

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CERTIFICATE OF SERVICE

I certify that on March 26, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify the foregoing document is being service this day on all counsel of record in this case via transmission of Notice of Electronic Filing generated by CM/ECF.

/s/ Harvey Bartle, IV
Harvey Bartle, IV